

### **Detailed Action**

This office action is in response to Applicant's communication filed on 3/22/06.

Claims 1-17 are pending in this application.

### **IDS**

The information disclosure statement (IDS) filed on 3/22/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### **Claim Rejections - 35 USC 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sinistri (WO 98/56750) and Carcasona et al. (US 5,391,775).

The instant claims are drawn to a method for purifying diacerein by the following steps: Step 1 is dissolving the diacerein in acetone/water. Step 2 is adjusting the pH with triethylamine in acetone. Step 3 is stirring the solution. Step 4 is adding an organic water immiscible-solvent. Step 5 is separating the organic phase from the acetone/water phase. Step 6 is repeating the extraction steps about 5 to 15 times. Step 7 is adding a strong acid and crystallizing the diacerein. Step 8 is collecting the diacerein by centrifugation or filtration.

Sinistri teaches steps 1, 2, 7 and 8. Sinistri teaches dissolving the diacerein in acetone/water, adjusting the pH with triethylamine in acetone, adding a strong acid, such as phosphoric acid, crystallizing the diacerein, collecting the diacerein by filtration, washing the product and drying (page 2, lines 21-30; page 3, lines 14-27; page 4, lines 14-31; page 5, lines 1, 18-31; page 6, lines 1-3) .

Sinistri is deficient in the sense that it does not teach steps 3-6.

Carcasona et al. teaches steps 3-5 and 7-8. Carcasona et al. teaches stirring the solution, adding an organic water immiscible-solvent, separating the organic phase from the acetone/water phase (column 7, lines 55-67; column 5, lines 5-61), adding sulphuric acid, washing and drying the precipitate (column 8, lines 14-30).

In reference to the limitation that the extraction steps would be repeated 5 to 15 times, it is the position of the examiner that one of ordinary skill in the art would use the appropriate number of extraction steps in optimizing the purity and yield of diacerein. Note that the art teaches counter-current extraction on a pulsed extraction column with at least 15 theoretical plates (column 7, lines 55-57).

In reference to the limitations for yields, purities, pH, proportions, times and solvents, it is the position of the Examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Thus it would be obvious in the optimization process to optimize the yields, purities, pH, proportions, times and solvents. The Applicant does not show any unusual and/or unexpected results for the limitations stated. Note that the prior art provides the same effect desired by Applicant, the purification of diacerein for the pharmaceutical industry.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to combine the teachings of Sinistri and Carcasona et al., to develop a process for the purification of crude diacerein by pH adjustment, extraction and crystallization. Absent any showing of unusual and/or unexpected results over applicant's particular process, the art obtains the same effect on the purity and yield of diacerein. The expected result would be the efficient purification of diacerein for the pharmaceutical industry in high yield and purity.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Patent Examiner  
Art Unit: 1621

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